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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,653	10/15/2001	Mark Thompson	MA-702D2	4237
23557	7590	11/03/2003		
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669				
			EXAMINER PROUTY, REBECCA E	
			ART UNIT	PAPER NUMBER
			1652	
			DATE MAILED: 11/03/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/977,653

Applicant(s)
Thompson et al.

Examiner
Rebecca Prouty

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 28, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 5, 8-10, 14, and 17-19 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 8-10, 14, and 17-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 2-4, 6-7, 11-13, 15-16, and 20-21 been canceled. Claims 1, 5, 8-10, 14, and 17-19 are still at issue and are present for examination.

Applicants' arguments filed on 7-28-03, paper No. 5, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 5, 8, 14, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are confusing as they depend from Claims 1 and 10 which are limited to peptide fragments of SEQ ID NO:2 or methods of use thereof but recite the proteins of SEQ ID NOS:6 and 8 or methods of use thereof. However, SEQ ID NOS: 6 and 8 are not peptide fragments of SEQ ID NO:2. Each of these proteins includes 2 additional amino acids at the N-terminus which are not present in SEQ ID NO:2. It is suggested that these claims be rewritten in independent format. For purposes of further examination, these claims will be interpreted as such.

The disclosure is objected to because of the following reasons: The description of Example 3 is confusing as to the

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structure of the truncated toxin produced. Example 3 states that the 86A1 toxin was digested with trypsin to produce a toxin which corresponds to the known sequence of the full length 86A1 toxin (SEQ ID NO:2) beginning at amino acid number 11. The Example then goes on to state that the fragment corresponds to residues 12-443 of SEQ ID NO:2. and then further states that the truncated toxin is referred to as R443 and has the sequence of SEQ ID NO:6. These descriptions are all inconsistent. Trypsin is well known in the art to cleave at the carboxy-terminal side of Arg or Lys residues. Residue number 11 of SEQ ID NO:2 is Arg while residue 12 is His. Thus one would expect a trypsin digest fragment to begin with residue 12 and not 11. Furthermore, as SEQ ID NO:6 includes 2 amino acids not present in SEQ ID NO:2 and does not include any of amino acid residues 11-13 of SEQ ID NO:2, it is unclear if R443 is referring to the trypsin digested 86A1 toxin or a related synthetic protein of SEQ ID NO:6.

Appropriate correction is required.

Claims 1, 9, 10, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

For the same reasons discussed in the objection to the specification above the recitation of "from amino acid 11 to

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amino acid 443 (or 390)" in these claims is confusing as it is unclear if the protein recited in the claims includes amino acid 11 of SEQ ID NO:2. As applicants remarks state that the claims "now refer to a segment of SEQ ID NO:2, as described in Example 3 and as tested in Example 4" and as described above one of skill in the art would recognize that the fragment described in Example 3 is amino acids 12-443 of SEQ ID NO:2, for further examination on the merits these claims are interpreted as reciting the amino acid segment of amino acids 12-443 of SEQ ID NO:2.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 10, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Payne et al. (US Patent 5,262,159) in

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view of Aronson et al., Nagamatsu et al., Pfannenstiel et al., Nicholls et al. and Wakibo et al. The rejection is explained in the previous Office Action.

Applicants argue that the claims are now limited to a segment of SEQ ID NO:2, as described in Example 3 and as tested in Example 4 and shown to have surprisingly increased toxicity. However, it is noted that the instant claims are not limited to the fragment shown in Example 4 to have unexpectedly increased toxicity. There is no reason presented by applicants to suggest that all insecticidal fragments of SEQ ID NO:2 will maintain the surprisingly increased toxicity of the specific fragment described in Example 3 of the specification. As such the rejection of the instant claims which are not commensurate in scope with the showing of unexpected results is maintained.

Claims 5, 8, 9, 14, 17, and 18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action. While the prior art suggests protease digestion of the 86A1 toxin to an insecticidal protease resistant core protein, and provides a reasonable expectation that the core would include small N-terminal deletions as well as C-terminal deletions of at least 85 amino acids, the prior art shows that the exact extent of deletions that can be made is unpredictable (particularly in this

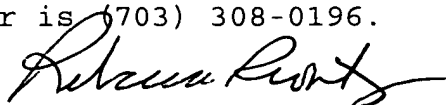
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case with respect to the N-terminus) and therefore selection of the specific fragments of SEQ ID NO:2 recited in claims 9 and 18 and included within the proteins of SEQ ID NOS: 6 and 8 would have been at best obvious to try. Furthermore, while the addition of a methionine residue at the N-terminus of an insecticidal fragment of the 86A1 toxin would have been obvious to one of ordinary skill in the art in order to provide for the recombinant expression of the toxin, the addition of the Gly residue at position 2 of both SEQ ID NOS:6 and 8 would not have been obvious. While the skilled artisan would not expect this additional residue to alter the activity, there does not appear to be any motivation to add an additional non-native amino acid to an insecticidal fragment of the 86A1 toxin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (703) 308-4000. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rebecca Prouty
Primary Examiner
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